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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,191	08/11/2001	Christophe Schilling	UCSD 99-093	6758

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,191	SCHILLING, CHRISTOPHE	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) *10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 20 March 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-8 are currently pending. Claims 9 and 16-27 have been cancelled. Claims 10-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 November 2004.

Claim Rejections - 35 USC § 101

Non-Statutory Subject Matter

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method of the instant claims is directed to analyzing the production of one or more selected metabolites of a biochemical reaction network. The method comprises steps in which reactions of a network are constructed from biochemical data, matrices are developed, linear equations are developed to form a solution space, and vectors are generated. The claims, as a whole, do not produce a result which is concrete, tangible, and useful. The claims merely encompass in silico data manipulation with no **specific** output that meets the concrete, tangible,

and useful criteria. No **specific** outcome is set forth in the claims such that the steps of the method produce a result that is immediately concrete, tangible, and useful. The claims must, **as a whole**, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention "transforms" an article or physical object to a different state or thing. [*The claimed invention in the instant case does not transform any physical object or article. The determination of sets corresponding to critical networks does not meet the criteria of a physical transformation of the instant method steps.*]

2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) [*The claimed invention in the instant application does not produce a concrete, tangible, and useful result*].

It is further noted that "the focus of the inquiry is whether the claim, considered as a whole, constitutes 'a practical application of an abstract idea." State Street, 149 F.3d at 1373, 47 USPQ2d at 1600. Thus, the question of whether a claim encompasses statutory subject matter should not focus on which category of subject matter a claim is directed (e.g. process or machine), "but rather on the essential characteristics of the subject matter, in particular its practical utility." State Street, 149 F.3d at 1375, 47 USPQ2d at 1602; see also AT&T, 172 F.3d at 1360, 50 USPQ2d at 1453.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." (1) "USEFUL RESULT" For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d

at 1230 (citing the Utility Guidelines with approval for interpretation of "specific" and "substantial"). (2) "TANGIBLE RESULT" The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no substantial practical application."). "[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection." Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."). In other words, the opposite meaning of "tangible" is "abstract." (3) "CONCRETE RESULT" Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is "irreproducible" claim should be rejected under section 101). The opposite of "concrete" is unrepeatable or unpredictable.

Applicant is invited to view the following web site for the text of the new Interim Guideline guidelines of November 2005:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

Note: Claim 8 is now included in these grounds of rejection, based upon the New Guidelines established November 2005.

Response to Applicant's Arguments

1. Applicant argues that "the process of determining reaction sets that affect the output of a metabolite of interest is a practical application having a concrete, useful, and tangible result because the method and the result can be used to produce biochemical products of interest". Applicant goes on to further describe examples of the use of the invention in biochemical production.

This is not persuasive. Applicant's arguments are directed to the usefulness of the instant invention, for example in the production of a therapeutic for disease treatment. However, the instant rejection is one of non-statutory subject matter, in which the following applies:

"It is further noted that "the focus of the inquiry is whether the claim, considered as a whole, constitutes 'a practical application of an abstract idea." State Street, 149 F.3d at 1373, 47 USPQ2d at 1600. Thus, the question of whether a claim encompasses statutory subject matter should not focus on which category of subject matter a claim is directed (e.g. process or machine), "but rather on the essential characteristics of the subject matter, in particular its practical utility." State Street, 149 F.3d at 1375, 47 USPQ2d at 1602; see also AT&T, 172 F.3d at 1360, 50 USPQ2d at 1453".

2. Applicant further argues that "predicting a design for re-engineering an organism to produce or augment the production of these biochemical products yields a concrete, useful, and tangible result having practical application".

This is not persuasive. The steps of the instant claims do not transform an article or physical object to a different state or thing. The result of the method is not one which is concrete, tangible, or useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a system of linear equations and inequalities defining the network, the method serving to when removed from the mathematically identify deletion sets of reactions that, network". It is unclear what applicant intends by this limitation, as the phrase is nonsensical. Clarification is requested.

Claim 1 recites "eliminate the capability of the network to produce a selected metabolite an improvement". It is unclear what Applicant intends, as the phrase seems to be missing a word or words. Clarification is requested.

Claim 1 recites "an improvement to the method comprising: where linear equations". It is unclear what steps encompass the "improvement" to the method. It is unclear whether the phrase beginning "where" is a step or a limitation of the network or a limitation of the data itself. Clarification is requested.

Claim 1 recites ""using the generating vectors". It is unclear whether the "use" of vectors is an active method step of calculating or modeling or if the reactions have been previously calculated or modeled and are now merely identified as being of interest. Clarification is requested.

Claim 1 recites "wherein the determined reaction sets". This limitation appears to limit the "determined" reaction steps. Is it the reaction sets that, when deleted, diminish the capability of the network or are the reactions sets those that, when stopped, affect the ability of the network? If the reaction set is stopped and affects the network by increasing production of a metabolite, then the two limitations are opposite and the claim is nonsensical. Clarification is requested.

Claim 6 recites "wherein the output of interest functional properties of interest in production network". It is unclear what is intended by this limitation, as the phrase is nonsensical. Clarification is requested.

Declaration

The Declaration under 37 CFR 1.132 of Schilling and Letscher, submitted 13 February 2006, has been considered. The Declaration is persuasive. The rejection under 35 USC 102(a) over Schilling et al. has been withdrawn in view of the submitted Declaration.

Conclusion

The outstanding rejections under 35 USC 112, 1st paragraph over claim 9 have been withdrawn in view of the cancellation of claim 9.

The outstanding rejections under 35 USC 112, 2nd paragraph have been withdrawn in view of the amendments to the claims. However, new rejections under 112, 2nd paragraph have been made, as set forth above.

The outstanding rejections under 36 USC 102(a) have been withdrawn in view of the declaration submitted under 37 CFR 1.132.

The outstanding rejections under 35 USC 103(a) have been withdrawn in view of the cancellation of claim 9.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

June 24, 2006
Lori A. Clow, Ph.D.
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Lori A. Clow
Patent Examiner